

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION: Lakshman R. SEHGAL, et al.

GROUP ART UNIT: 1642

SERIAL NUMBER: 10/785,156

EXAMINER.

FILED: February 25, 2004



FOR: THERAPEUTIC APPLICATIONS OF THROMBOMODULIN GENE VIA VIRAL AND NON-VIRAL VECTORS

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. 1.97

Assistant Commissioner for Patents
PO BOX 1450
ALEXANDRIA, VA 22313-1450

Sir:

Applicant(s) wish(es) to disclose the following information.

REFERENCES

- Applicant(s) wish(es) to make of record the documents listed on the attached Form PTO-1449. Copies of the listed documents are attached, where required, as are either statements of relevancy or any readily available full or partial English translations of any non-English-language documents.

RELATED CASES

- Attached is a list of Applicant's(s') pending applications and issued patents which may be related to the present application. Copies of the documents, where required, are attached along with Form PTO-1449.

CERTIFICATION

The undersigned certifies that

- each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign or international patent office in a counterpart foreign or international application for the first time (to the knowledge of the undersigned, having made reasonable inquiry) not more than three months prior to the filing of this statement.
- no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign or international patent office in a counterpart foreign or international application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this statement.

BASIS FOR CONSIDERATION

This Information Disclosure Statement is filed:

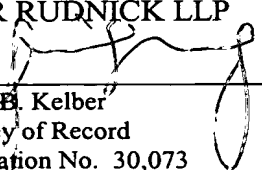
- without fee and within three months of the filing date of the application.
- without fee and within three months of the date of entry of the U.S. national stage.
- without fee and before the mailing date of a first Office Action on the merits (to the knowledge of the undersigned).
- without fee and with the appropriate certification above.
- without fee and with a new CPA application.
- without fee and with a Request for Continued Examination.
- with fee and before the mailing date of any Final Office Action, Notice of Allowance or an action that otherwise closes prosecution (to the knowledge of the undersigned).
- with fee, appropriate certification above, and before payment of the Issue Fee.

DEPOSIT ACCOUNT

- Please charge any additional fees for the papers being filed herewith and for which no check is enclosed herewith, or credit any overpayment to Deposit Account No. 50-1442.

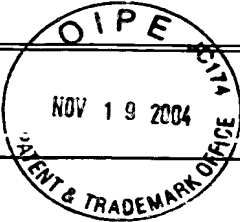
Respectfully submitted,

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Form PTO 1449 (Modified)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	DOCKET NO.		SERIAL NO.
		3840-006-27		10/785,156
		LIST OF REFERENCES CITED BY APPLICANT (Use Several Sheets if Necessary)		APPLICANT
Lakshman R. SEHGAL et al.				
		FILING DATE	GROUP ART UNIT	
		February 25, 2004	1642	

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	AA	4,868,116	09/19/89	Morgan et al.			
	AB	5,061,688	10/29/91	Beissinger et al.			
	AC	5,339,346	08/16/94	White			
	AD	5,438,041	08/01/95	Zheng et al.			
	AE	5,449,614	09/12/95	Danos et al.			
	AF	5,661,033	08/26/97	Ho et al.			
	AG	5,919,619	07/06/99	Tullis			
	AH	5,985,846	11/16/99	Kochanek et al.			
	AI	6,083,750	07/04/00	Chamberlain et al.			
	AJ	6,207,455	03/27/01	Chang			
	AK	6,328,958	12/11/01	Amalfitano et al.			
	AL	6,334,194	12/25/01	Hihara			
	AM	6,335,011	01/01/02	Podsakoff et al.			
	AN	6,342,214	01/29/02	Tryggvason et al.			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION YES NO
	AO	WO99/14346			
	AP	WO01/29058			

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	AQ	Ausbel, et al., (eds) Greene Publishing Associates, "Current Protocols in Molecular Biology", Sections 9.10-9.14, 1989.
	AR	Ng, et al., "Development of a FLP/φ System for Generating Helper-Dependent Adenoviral Vectors", Molecular Therapy, Vol. 3, No. 5, pp. 809-815, 2001.
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EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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	AT	Chen, et al., "Low-Dose Vaccinia Virus-Mediated Cytokine Gene Therapy of Glioma", Journal of Immunotherapy, Vol. 24, pp. 46-57, 2001.		
	AU	Chen, et al., "Gene therapy for brain tumors: Regression of experimental gliomas by adenovirus-mediated gene transfer <i>in vivo</i> ", Proc. Natl. Acad. Sci. USA, Vol. 91, pp. 3054-3057, 1994.		
	AV	Cui, et al., "Plasmid DNA-Entrapped Nanoparticles Engineered from Microemulsion Precursors" In Vitro and in Vivo Evaluation", Bioconjugate Chem., Vol. 13, pp. 1319-1327, 2002.		
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	AX	Wen, et al., "Human Thrombomodulin: Complete cDNA Sequence and Chromosome Localization of the Gene", Biochemistry, Vol. 26, No. 14, pp. 4350-4357, 1987.		
	AY	Gossen, et al., "Transcriptional Activation by Tetracyclines in Mammalian Cells", Science, Vol. 268, pp. 1766-1769, 1995.		
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	BA	Fink, et al., "Gene Transfer to Neurons Using Herpes Simplex Virus-Based Vectors", Annual Rev. Neurosci, Vol. 19, pp. 265-287, 1996.		
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	BD	Haj-Ahmand, et al., "Development of a Helper-Independent Human Adenovirus Vector and Its Use in the Transfer of the Herpes Simplex Virus Thymidine Kinase Gene", J. Virol., Vol. 57, pp. 267-273, 1986.		
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	BF	Kay, et al., "Evidence for gene transfer and expression of factor IX in haemophilia B patients treated with an AAV vector", Nature Genetics, Vol. 24, pp. 257-261, 2000.		
	BG	Kessler, et al., "Gene delivery to skeletal muscle results in sustained expression and systemic delivery of a therapeutic protein", Proc. Natl. Acad. Sci. USA, Vol. 93, pp. 14082-14087, 1996.		
	BH	Kistner, et al., "Doxycycline-mediated quantitative and tissue-specific control of gene expression in transgenic mice", Proc. Natl. Acad. Sci. USA, Vol. 93, pp. 10933-10938, 1996.		
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	CA	Magari, et al., "Pharmacologic Control of a Humanized Gene Therapy System Implanted into Nude Mice", J. Clin. Invest., Vol. 100, pp. 173-206, 1997.			
	CB	Miller, "Progress Toward Human Gene Therapy", Blood, Vol. 76, pp. 271-278, 1990.			
	CC	Muzyczka, et al., "Use of Adeno-Associated Virus as a General Transduction Vector for Mammalian Cells", Curr. Topics in Micro. and Immunology, Vol. 158, pp. 97-129, 1992.			
	CD	Naldini, et al., "In Vivo Gene Delivery and Stable Transduction of Nondividing Cells by a Lentiviral Vector", Science, Vol. 272, pp. 263-267, 1996.			
	CE	No, et al., "Ecdysone-inducible gene expression in mammalian cells and transgenic mice", Proc. Natl. Acad. Sci. USA, Vol. 93, pp. 3346-3351, 1996.			
	CF	Pruchnic, et al., "The Use of Adeno-Associated Virus to Circumvent the Maturation-Dependent Viral Transduction of Muscle Fibers", Human Gene Therapy, Vol. 11, pp. 521-536, 2000.			
	CG	Ragot, et al., "Efficient adenovirus-mediated transfer of a human minidystrophin gene to skeletal muscle of <i>mdx</i> mice", Nature, Vol. 361, pp. 647-650, 1993.			
	CH	Romano, et al., "Latest Developments in Gene Transfer: Achievements, Perspectives, and Controversies over Therapeutic Applications", Stem Cells, Vol. 18, pp. 19-39, 2000.			
	CI	Ropert, "Liposomes as a gene delivery system", Brazilian Journal of Medical and Biological Research, Vol. 32, pp. 163-169, 1999.			
	CJ	Sakhujia, et al., "Optimization of the Generation and Propagation of Gutless Adenoviral Vectors", Human Gene Therapy, Vol. 14, pp. 243-254, 2003.			
	CK	Samulski, et al., "Helper-Free Stocks of Recombinant Adeno-Associated Viruses: Normal Integration Does Not Require Viral Gene Expression", Journal of Virology, Vol. 63, No. 9, pp. 3822-3828, 1989.			
	CL	Schwarze, et al., "In Vivo Protein Transduction: Delivery of a Biologically Active Protein into the Mouse", Science, Vol. 285, pp. 1569-1572, 1999.			
	CM	Song, et al., "Sustained secretion of human alpha-1 antitrypsin from murine muscle transduced with adeno-associated virus vectors", Proc. Natl. Acad. Sci. USA, Vol. 95, pp. 14384-14348, 1998.			
	CN	Suzuki, et al., "Structure and expression of human thrombomodulin, a thrombin receptor on endothelium acting as a cofactor for protein C activation", EMBO Journal, Vol. 6, pp. 1891-1897, 1987.			
	CO	Umaña, et al., "Efficient FLPe recombinase enables scalable production of helper-dependent adenoviral vectors with negligible helper-virus contamination", Nature Biotechnology, Vol. 19, pp. 582-585, 2001.			
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	DA	Wahlfors, et al., "Evaluation of recombinant alphaviruses as vectors in gene therapy", Gene Therapy, Vol. 7, pp. 472-480, 2000.	
	DB	Wang, et al., "A regulatory system for use in gene transfer", Proc. Natl. Acad. Sci. USA, Vol. 91, pp. 8180-8184, 1994.	
	DC	Wang, et al., "Ligand-inducible and liver-specific target gene expression in transgenic mice", Nature Biotechnology, Vol. 15, pp. 239-243, 1997.	
	DD	Yamashita, et al., "Electroporation-mediated <i>Interleukin-12</i> Gene Therapy for Hepatocellular Carcinoma in the Mice Model", Cancer Research, Vol. 61, pp. 1005-1012, 2001.	
	DE	Ye, et al., "Regulated Delivery of Therapeutic Proteins After in Vivo Somatic Cell Gene Transfer", Science, Vol. 283, pp. 88-91, 1999.	
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	DG	Xiao, et al., "Efficient Long-Term Gene Transfer into Muscle Tissue of Immunocompetent Mice by Adeno-Associated Virus Vector", Journal of Virology, Vol. 70, No. 11, pp. 8098-8108, 1996.	
	DH	Xiao, et al., "Adeno-Associated Virus as a Vector for Liver-Directed Gene Therapy", Journal of Virology, Vol. 72, No. 12, pp. 10222-10226, 1998.	
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	DK	Kibbe, et al., "Handbook of Pharmaceutical Excipients", 3 rd Edition, Pharmaceutical Press London, UK, 2000.	
	DL	Lee, et al., "Crit. Rev. Ther. Drug Carrier Systems, Vol. 14, pp. 173-206, 1997.	
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